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MA, JAMESON Q				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,993

Applicant(s)

DOSMANN, ANDREW J.

Examiner

JAMESON Q. MA

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-13 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Huhn et al. (US 2002/0145121).

Regarding claim 21, Huhn discloses a format comprising a first format member (lid 3) comprising a first inner surface and a platform (surface 3''') extending a distance from said inner surface, said platform further extending in a direction substantially perpendicular to said inner surface (see fig. 1, the bottom of surface 3''' has extended in a perpendicular direction from the horizontal plane of lid 3), and a second format member (body 2) comprising a second inner surface and a well (4^V) disposed within said second inner surface, said well being shaped to accept said platform within said well.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 4-5, 7-13, 15, 17-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huhn et al. (US 2002/0145121).

Independent claims 1, 8, and 15 are addressed together.

Regarding independent claim 1, Huhn discloses a format for optical testing of a sample and a method of manufacturing a format for optical testing comprising:

- a first format member (see Fig. 1: lid 3 is viewed as a first format member) comprising a first inner surface and a platform (see Fig. 1: reference 3''') extending a distance from said inner surface;
- a second format member (see Fig. 1: body 2 is viewed as a second format member) comprising a second inner surface and a well (see Fig 1: portion 4^V is viewed as a well) disposed within said second inner surface, said well being shaped to accept said platform of said first format member within said well.
- a sample fill nose disposed within said second format member and extending from a sample collection opening at a first end of said sample fill nose to intersect with said well at a second end of said sample fill nose (see fig. 1 and [0038]: the microchannel (and therefore the sample fill nose) is worked into the body (second format member)).
- a vent disposed within said second format member and extending along said second inner surface from a vent opening at a first end of said vent to intersect with said well at a second end of said vent (see fig. 1 and [0038]: the microchannel (and therefore the vent) is worked into the body (second format member)).

Regarding independent claim 8, Huhn discloses a format for optical testing of a sample comprising:

- a first format member (see Fig. 1: cap 3 is viewed as a first format member) comprising a first inner surface and a platform extending to a platform (see Fig. 1: reference 3'') height from said inner surface;
- a second format member (see Fig. 1: body 2 is viewed as a second format member) comprising a second inner surface and a well (see Fig 1: portion 4^V is viewed as a well) disposed within said second inner surface and extending a well depth below said second inner surface, said well being shaped to accept said platform of said first format member within said well thereby forming a sample testing region;
- a sample fill nose (see Fig. 1: lateral portion 4' is viewed as a sample fill nose) extending from a sample collection opening at a first end of said sample fill nose to said well at a second end of said sample fill nose;
- a vent (see Fig. 1: lateral portion 4'' is viewed as a vent) extending from a vent opening at a first end of said vent to said well at a second end of said vent.

Regarding independent claim 15, Regarding claim 15, Huhn discloses method of manufacturing a format for optical testing, the method comprising the acts of:

- providing a first format member (see Fig. 1: body 2 is viewed as a second format member) comprising a first inner surface and a platform (see Fig. 1: reference 3'') extending to a platform height above said first inner surface;
- providing a second format (see Fig. 1: body 2 is viewed as a second format member) member comprising:
 - a second inner surface and a well (see Fig 1: portion 4^V is viewed as a well)

disposed within said second inner surface mad extending to a well depth below said second inner surface, said well depth being greater than said platform height;

- a sample fill nose notch terminating at said well (see Fig. 1: lateral portion 4' is viewed as a sample fill nose, which terminates at 4''");
- a vent notch terminating at said well (see Fig. 1: lateral portion 4'' is viewed as a vent, which terminates at 4^{IV}); and
- joining said first format member to said second format member by inserting said platform of said first format member into said well of said second format member, thereby forming a sample testing region (see [0035] and Fig. 1).

None of claims 1, 8, and 15 address that the sample fill nose has a cross section or width different from a vent cross-section or width.

However, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the width or cross-section of the sample fill nose or the vent, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claim 10, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the format wherein said sample fill nose is adapted to transport a volume of said sample from said sample collection opening to said sample testing region via capillary action (see [0036]: reference 4 is referred to as a capillary microchannel, implying that sample volumes are transported via capillary action).

Regarding claims 22-24, modified Huhn discloses all of the claim limitations as set forth above. Modified Huhn fails to disclose the format wherein the vent has a width of cross-sectional area greater than the sample fill nose width or cross-sectional area.

However, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the width or cross-section of the sample fill nose or the vent, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claim 25, modified Huhn discloses all of the claim limitations as set forth above. Huhn additionally discloses the format wherein said platform extends in a

direction substantially perpendicular to said inner surface (see fig. 1, the bottom of surface 3''' has extended in a perpendicular direction from the horizontal plane of lid 3).

Regarding claims 4-5, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the format:

- wherein said vent intersects with said well at an area approximately opposing an intersection of said sample fill nose with said well (see Fig. 1).
- wherein said platform extends from said first inner surface to a platform height and wherein said well extends within said second format member to a well depth greater than said platform height, thereby forming a sample testing region for accepting said sample (see Fig. 1).

Regarding claim 7, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the optical format wherein said sample testing region has a sample testing region volume and further comprising a fill nose disposed within said second format member and extending from a sample collection opening at a first end to said sample testing region at a second end. However, Huhn does not specifically disclose said fill nose having a fill nose volume greater than said sample testing region volume, thereby ensuring that sufficient sample volume is available to fill the sample testing region.

Since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the volumes of the fill nose and the sample testing region, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally

recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claim 9, modified Huhn discloses all of the claim limitations as set forth above. Huhn also discloses a cap with a prism shaped elevation which is viewed as a platform ([0039]). Huhn does not specifically disclose the format wherein said platform is cylindrical and has a platform diameter and said well is cylindrical and has a well diameter greater than said platform diameter.

With respect to claim 9, Huhn does not disclose a cylindrical shape of the platform, but said reference does disclose said platform having a prismatic shape. There is no significant difference between a prismatic or cylindrical shaped platform. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the platform of Huhn to have a cylindrical shape, as such modification would involve a mere change in configuration. It has been held that a change in configuration of shape of a device is obvious, absent persuasive evidence that a particular configuration is significant. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the diameters of the platform and the well, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claims 11-12, modified Huhn discloses all of the claim limitations as set forth above. However, Kuhn does not explicitly disclose the format wherein the volume of said sample is approximately 50 nl or within the range from approximately 5 nl to approximately 1000 nl.

Regarding limitations recited in claims 11-12 which are directed to the volume of said sample, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states

"Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding claim 13, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the format wherein said vent opening is provided on an opposite side of said format from said sample collection opening (see Fig. 1).

Regarding claim 17, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the method of manufacturing a format for optical testing wherein said sample fill nose notch approximately opposes said vent notch across said well (see Fig. 1: the two opposing channels 4' and 4", viewed as a sample fill nose and vent respectively, terminate at opposite sides of indentation 4^V).

Regarding claim 18, modified Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses that lid (first format member) is placed over the basic body of the microfluidic component (second format member). However, Huhn does not explicitly disclose the method of manufacturing the format further comprising providing adhesive on one or both of said first and second format members.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to use a form of adhesive to combine the two separate format members as disclosed by Huhn, because doing so would amount to nothing more than choosing from a finite number of identified and predictable solutions of combining components.

Regarding claims 19-20, modified Huhn discloses all of the claim limitations as set forth above. However, Huhn does not disclose the method of manufacturing a

format wherein said vent notch and said fill nose notch have rectangular cross-sections. Huhn does disclose in its specification that microfluidic components feature characteristic cross dimensions of a diameter or a width and height (see [0004]). These imply circular or rectangular cross sections.

It would have been obvious to one of ordinary skill in the art to make the vent notch and sample fill notch to have a rectangular cross-section, because doing so would result in nothing more than choosing from a finite number or identified and predictable solutions of cross-section shapes.

5. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huhn et al. (US 2002/0145121) as applied to claims 1, 4-5, 7-13, 15, 17-20, and 22-25 above, and further in view of Lilja et al. (US 4,088,448).

Regarding claim 6, Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the format that can be analyzed by a photo transmitter and photo receiver (see [0043]). However, Huhn does not explicitly disclose the format wherein said platform is provided with a reagent thereon for reacting with said sample.

Lilja teaches an optical cuvette with a cavity (see Fig. 2: 11) that is supplied with a reagent to react with a sample drawn into the cavity (see C2/L47-52).

Huhn and Lilja are analogous because both references are directed to optical devices for accepting liquid samples.

It would have been obvious to one of ordinary skill in the art at the time of invention to coat the platform of Huhn, with a reagent as taught by Lilja, in order to provide additional functionality to the device as disclosed by Huhn.

Regarding claim 16, Huhn discloses all of the claim limitations as set forth above. Additionally, Huhn discloses the format that can be analyzed by a photo transmitter and photo receiver (see [0043]). However, Huhn does not explicitly disclose the method of manufacturing a format further comprising applying a testing reagent to said platform.

Lilja teaches an optical cuvette with a cavity (see Fig. 2: 11) that is supplied with a reagent to react with a sample drawn into the cavity by evaporation, freeze-drying, spraying, screen-printing or in another suitable manner (see C2/L47-52).

Huhn and Lilja are analogous because both references are directed to optical devices for accepting liquid samples.

It would have been obvious to one of ordinary skill in the art at the time of invention to coat the platform of Huhn, with a reagent as taught by Lilja, in order to provide additional functionality to the device as disclosed by Huhn.

Response to Arguments

6. Applicant's arguments filed 12/10/2008 have been fully considered but they are not persuasive. Applicant's assertion that Huhn lacks disclosure of different cross-sectional geometries for the sample fill nose and vent and teaches away from such a feature is noted. However, the fact that Huhn discloses the microchannel 4 as substantially constant is not a statement that teaches away from such a modification. Such a modification would not cause the device disclosed by Huhn to fail. Further, as noted in the prior office action and in the current office action, without a showing of unexpected results, such a modification of dimension and size of a component would still be rendered obvious to one of ordinary skill in the art. Applicant's assertion that

Huhn teaches away from a platform extending in a direction substantially perpendicular to an inner surface is noted. However, the examiner notes that while surfaces 3' and 3'' are inclined at an angle of 45 degrees, the bottom of surface 3''' has been shown in figure 1 to extend in a perpendicular direction from the horizontal plane (inner surface) of lid 3.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-R 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

JM
March 10, 2009